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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/242,540	02/18/1999	ELFI BIEDERMANN	64978	1192

7590 11/15/2001
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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT PAPER NUMBER

1624

DATE MAILED: 11/15/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/242,540

Applicant(s)
BIEDERMANN et al.

Examiner
Brenda Coleman

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 7, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-51 and 55-82 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-51 and 55-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

Art Unit: 1624

DETAILED ACTION

Claims 42-51 and 55-82 are pending in the application.

This action is in response to applicants' amendment filed September 7, 2001. Claims 52-54 have been canceled, claims 42-51, 56, 64 and 65 have been amended and claims 68-82 are newly added.

Response to Amendment

Applicant's amendments filed September 7, 2001 have been fully considered with the following effect:

1. The applicant's amendments are sufficient to overcome the 35 USC § 112, second paragraph rejections labeled b), f), as) and at) maintained in the last office action. However, with regards to the 35 U.S.C. § 112, second paragraph rejection labeled j), the applicant's failed to comment on the rejection which was maintained in the last office action.

Claims 42-46, 55-65 and newly added claims 72-76 and 78-81 are rejected under 35 § U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record.

2. With regards to the 35 U.S.C. § 103 rejection over Goto et al., EP 0 330 026 (U.S. equivalent 5,169,856), the applicant's failed to comment on the rejection which was maintained in the last office action.

Art Unit: 1624

Claims 42-46, 56-58, 62 and newly added claims 68 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goto et al., EP 330 026. For reasons of record.

3. With regards to the obviousness-type double patenting rejection of claims 42-46 and 52-67 over claims 41-47 and 54-59 of copending Application NO. 09/216,075, the applicants' failed to comment on the rejection which was maintained in the last office action.

Claims 42-46 and 55-82 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 41-47 and 54-79 (upon further review of the claims) of copending Application No. 09/216,075. For reasons of record.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. With regards to the obviousness-type double patenting rejection of claims 42-67 over claims 33-35 of copending Application NO. 09/216,482, failed to comment on the rejection which was maintained in the last office action.

Claims 42-51 and 55-82 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20-37 (upon further review of the claims) of copending Application No. 09/216,482. For reasons of record.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art Unit: 1624

5. The applicant's amendments are sufficient to overcome the 35 USC § 112, second paragraph rejections labeled a), b), c) and d) of the last office action. However, with regards to the 35 U.S.C. § 112, second paragraph rejection labeled e), the applicant's failed to comment on the rejection which was made in the last office action.

Claims 64-67 and newly added claims 72-82 are rejected under 35 § U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record.

6. With regards to the 35 U.S.C. § 102 rejection by Goto et al., U.S. Patent Number 5,169,856, the applicant's failed to comment on the rejection which was maintained in the last office action.

Claims 45 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Goto et al., U.S. Patent Number 5,169,856. For reasons of record.

In view of the amendment dated September 7, 2001, the following new grounds of rejection apply:

Information Disclosure Statement

7. One of the journal articles, i.e. R. Fischer, "Allgemeine Pathologie und Pathologische Anatomie" is missing the publication date which is required for citation upon allowance of the application. The applicants' are reminded that the publication date is needed to complete the record.

Art Unit: 1624

Election/Restriction

8. Claims 42-44, 46, 55-68 and 71-82 are rejected as being drawn to an improper Markush group. The recited compounds, while possessing a common utility, differ widely in structure and are not art-recognized equivalents and are thus, independently distinct for the reasons set forth in the restriction requirement. The Markush group represented by the term E has variably different definitions, rendering the claims clearly improper.

Specification

9. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The variables in claims 70 and 71 for formula (I) have been moved, i.e. R² which is bound to the pyridine ring in the specification is bound to the N atom in claims 70 and 71; R³ which is bound to the pyridine ring in the specification is now within the definition of the substituents of D; R⁸ which is within the definition of bridged R¹R² in the specification is now bound to E; all of the substituents of the G moieties are also different than those defined in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

Art Unit: 1624

make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 42-46 and 55-63, 68, 70 and 71 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the compounds of formula (I) where "pharmaceutically acceptable salts" were included is not described in the specification.

Applicant is required to cancel the new matter in the reply to this Office action.

11. Claims 69 and 70 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the compounds of formula (I) where D is "a substituted 1,3,5-hexatrienylene which is substituted once or twice by C₁-C₃-alkyl or hydroxy" were included is not described in the specification.

Applicant is required to cancel the new matter in the reply to this Office action.

12. Claims 71, 77 and 82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the compounds of formula (I) where G is

Art Unit: 1624

“piperidin-3-ylmethyl” or “piperidin-1-ylmethyl” are not described in the specification. See page 70, lines 5-6 in claim 71; page 106, lines 5-6 in claim 77; and page 141, lines 5-6 in claim 82.

Applicant is required to cancel the new matter in the reply to this Office action.

13. Claims 71, 77 and 82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the compounds of formula (I) where D is “CH₂CH=” on page 70, line 8 and “CH₂CH₂CH₂CH=” on page 75, line 4 and page 96, line 2 are not described in the specification. See also claim 77, page 106, line 8, page 111, line 4 and page 132, line 2; and claim 82, page 141, line 8, page 146, line 4 and page 167, line 2.

Applicant is required to cancel the new matter in the reply to this Office action.

14. Claims 71, 77 and 82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the compounds of formula (I) where E is partially unsaturated pyridine on page 75, line 6 is not described in the specification. See also claim 77, page 111, line 6 and claim 82, page 146, line 6.

Applicant is required to cancel the new matter in the reply to this Office action.

Art Unit: 1624

15. Claims 71, 77 and 82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the compounds of formula (I) where G is pyridylbenzopyran on page 83, line 4 is not described in the specification. See also claim 77, page 119, line 5 and claim 82, page 154, line 4.

Applicant is required to cancel the new matter in the reply to this Office action.

16. Claims 71, 77 and 82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the compounds of formula (I) where G is $\text{-C(=O)-C(=O)-3-(1-phenyl-pyrrole)}$ on page 86, line 5 is not described in the specification. See also claim 77, page 122, line 5 and claim 82, page 157, line 5.

Applicant is required to cancel the new matter in the reply to this Office action.

17. Claims 71, 77 and 82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the compounds of formula (I) where G is

Art Unit: 1624

-C(=O)-N(isopropyl)₂ on page 90, line 6 is not described in the specification. See also claim 77, page 126, line 6 and claim 82, page 161, line 6.

Applicant is required to cancel the new matter in the reply to this Office action.

18. Claims 71, 77 and 82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the compounds of formula (I) where G is -C(=O)-NH(furan-2-ylmethyl) on page 91, line 2 is not described in the specification. See also claim 77, page 127, line 2 and claim 82, page 162, line 2.

Applicant is required to cancel the new matter in the reply to this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

19. Claims 42-47 and 55-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 42, 45, 55-69 and 72-82 are vague and indefinite in that it is not known what is meant by the moiety (CH=CH)- in the definition of bridged R¹R². There is only one point of attachment while the other moieties indicate two.

Art Unit: 1624

- b) Claims 42, 43, 55-69, 72-76 and 78-81 are vague and indefinite in that it is not known what is meant by the variable Ar_2 which is not defined within the claim.
- c) Claims 42, 43, 55-69, 72-76 and 78-81 are vague and indefinite in that it is not known what is meant by the definition of Ar^2 and the substituents for Ar^2 when there is no variable Ar^2 in the claim.
- d) Claims 42-44, 55-68, 72-76 and 78-81 are vague and indefinite in that it is not known what is meant by “wherein two adjacent groups of an aromatic ring in the substituted C1-C6 alkoxy may form an additional ring”.
- e) Claim 43 is vague and indefinite in that it is not known what is meant by “an isosterically replaced C1 to C8 group”.
- f) Claim 43 is vague and indefinite in that it is not known what is meant by “bound directly or over a methylene group, furyl, thienyl, pyrrolyl, oxazolyl,...” in lines 4+ on pages 13-14.
- g) Claim 44 is vague and indefinite in that it is not known what is meant by “an isosterically replaced C2 to C8 group”.
- h) Claim 44 is vague and indefinite in that it is not known what is meant by the “and” which appears in the fifth line from the bottom of page 19 indicating the near end of the definition, which is not so.

Art Unit: 1624

- i) Claim 44 is vague and indefinite in that it is not known what is meant by “bound directly or over a methylene group, furyl, thienyl, pyrrolyl, oxazolyl,....” beginning in third line from the bottom on page 19.
- j) Claims 44 and 45 recite the limitation “-NR¹²R¹⁴” in definition of G. There is insufficient antecedent basis for this limitation in the claim.
- k) Claim 44 is vague and indefinite in that it is not known what is meant by the moiety “1,2,3,4-tetrahydro-9H-pyrido[3,4-b]indol”. It is believed that the applicants’ intended 1,2,3,4-tetrahydro-9H-pyrido[3,4-b]indole.
- l) Claim 45 is vague and indefinite in that it is dependent upon a canceled claim, i.e. claim 22.
- m) Claim 45 is vague and indefinite in that it is not known what is meant by C₂-C₆-alkylene wherein the double bond is to ring E in the definition of D on pages 22-23. It is not known what double bond.
- n) Claim 45 is vague and indefinite in that it is not known what is meant by “an isosterically replaced C2 to C6 group”.
- o) Claim 45 is vague and indefinite in that it is not known what is meant by “bound directly or over a methylene group, furyl, thienyl, pyrrolyl, oxazolyl,....” beginning in line 10 on page 24.

Art Unit: 1624

- p) Claim 46 is vague and indefinite in that it is not known what is meant by C₂-C₆-alkylene wherein the double bond is to ring E in the definition of D on page 26. It is not known what double bond.
- q) Claim 47 is vague and indefinite in that it is dependent upon a canceled claim, i.e. claim 4.
- r) Claim 68 is vague and indefinite in that it is not known what is meant by the second appearance of hydrogen in the definition of R¹².
- s) Claim 68 is vague and indefinite in that it is not known what is meant by the “and” which appears in the fourth line of page 54 indicating the near end of the definition, which is not so.
- t) Claim 69 is vague and indefinite in that it is not known what is meant by R⁹ is “selected from selected from the group.....” on page 58.
- u) Claim 69 is vague and indefinite in that it is not known what is meant by “the N, S and O being either bound directly to or over a methylene group” in the definition of R¹² on page 60.
- v) Claim 70 is vague and indefinite in that the list of substituents for the variable A includes C₄-C₆-alkenylene which is embraced by C₂-C₆-alkenylene, and thus results in double inclusion. See Ex parte White 127 USPQ 261.
- w) Claim 70 is vague and indefinite in that it is not known what is meant by R³ is “selected from selected from the group.....” on page 64.

Art Unit: 1624

- x) Claim 70 is vague and indefinite in that it is not known what is meant by R within the definition of G for which there is no definition in the claim.
- y) Claim 70 is vague and indefinite in that it is not known what is meant by “C₃-C₆ alkenyl” which appears twice in the definition of R⁴.
- z) Claim 71 is vague and indefinite in that the moieties on page 80, lines 2-4 are duplicates of the moieties on page 79, lines 2-3.
- aa) Claim 71 is vague and indefinite in that the moiety on page 81 is a duplicate of the moiety on page 80, line 1.
- ab) Claim 71 is vague and indefinite in that the moiety on page 88, in line 4 is a duplicate of the moiety on page 88, in line 3.
- ac) Claim 77 is vague and indefinite in that the moieties on page 116, lines 2-4 are duplicates of the moieties on page 115, lines 2-3.
- ad) Claim 77 is vague and indefinite in that the moiety on page 117 is a duplicate of the moiety on page 116, line 1.
- ae) Claim 77 is vague and indefinite in that the moiety on page 124, in line 4 is a duplicate of the moiety on page 124, in line 3.
- af) Claim 82 is vague and indefinite in that the moieties on page 151, lines 2-4 are duplicates of the moieties on page 150, lines 2-3.
- ag) Claim 82 is vague and indefinite in that the moiety on page 152 is a duplicate of the moiety on page 151, line 1.

Art Unit: 1624

- ah) Claim 82 is vague and indefinite in that the moiety on page 159, in line 4 is a duplicate of the moiety on page 159, in line 3.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays and Tuesdays from 9:00 AM to 3:00 PM and from 5:30 PM to 7:30 PM and on Wednesday thru Friday from 9:00 AM to 6:00 PM.

Art Unit: 1624

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Brenda Coleman
Primary Examiner AU 1624
November 9, 2001